by Kimura and Suzuki (1981), other *in vivo* studies are limited to the blood glucose-lowering effect of ginseng root extracts in type 1 diabetes models.

Other investigators have reported on the pharmacological effects of ginseng leaves in alloxan diabetic mice. Extracts of ginseng root and leaves increased basal plasma insulin levels and glucose-dependent insulin secretion, and prevented lipid peroxidation in the pancreas (Davydov *et al.*, 1990). Molokovskii *et al.* (1989) reported that ginseng root and leaf extracts lowered blood glucose levels, and increased insulin and liver glycogen. Ginseng leaf extract was also reported to decrease the hypoglycemia caused by insulin infusion (Molokovskii and Barnaulov, 1986).

Two clinical trials that tested anti-diabetic effects of ginseng root have been reported. In a double-blind placebo-controlled study of ginseng root therapy for type 2 diabetes, Sotaneimi *et al.* (1995) reported that treatment with ginseng (species unknown) elevated mood, improved psychological performance, and reduced fasting blood glucose and body weight. A recent short-term clinical study by Vuksan *et al.* (2000) reported that American ginseng reduced post-prandial hyperglycemia in non-diabetic subjects, and in subjects with type 2 diabetes. The mechanisms of anti-hyperglycemic actions of ginseng have not been determined.

SUMMARY OF THE INVENTION

The inventors describe herein pharmaceutical compositions comprising an active compound of ginseng berry extract and/or compounds found in ginseng berry that are useful as anti-hyperglycemic and anti-obesity agents. In certain embodiments of the invention, the inventors describe methods of screening for the active compound of ginseng berry extract. The present inventors envision that pharmaceutical compositions described herein may be able to modulate glucose homeostasis in an individual suffering from type 2 diabetes.

In specific embodiments of the present invention, pharmaceutical compositions are provideded comprising at least one active compound of from a berry from a plant of the Panax genus and a pharmaceutically acceptable carrier. The preferred species of ginseng in the present invention is *Panax ginseng* (Asian ginseng) or *Panax quinquefolius* (American ginseng). More specifically, the presently preferred Asian ginseng or *Panax ginseng* can be cultivated in Northeast China and the American ginseng or *Panax quinquefolius* can be cultivated in Wisconsin, U.S.A.

In certain embodiments, the active compound of the compositions comprises an anti-hyperglycemic constituent or an anti-obesity constituent or both an anti-hyperglycemic constituent and an anti-obesity constituent. More particularly, for example, the active compound comprises a ginsenoside. The single ginsenside may be Re. Other exemplary ginsenosides include, but are not limited to Rg1, Rb1, Rc, Rb2 or Rd. It is also contemplated that the active compound comprises at least two ginsenosides. Yet further, the active compound may comprise non-ginsenoside components of ginseng berry extract or may be ginsenoside free. One of skill in the art will recognize that the non-ginsenoside constituents may include, but are not limited to polysaccharides, peptides, polyacetylenic alcohols and fatty acids.

Another specific embodiment of the present invention provides a method of using the pharmaceutical compositions. The compositions may be administered to an animal suffering from non-insulin dependent diabetes, type 2 diabetes. The animal may be a mammal, such as a human. More specifically, in some embodiments, the human may be obese. Other exemplary mammals that can be treated using the present invention include, but are not limited to mice, rats, dogs, cats, guinea pigs, rabbits and monkeys.

In a further embodiment, the compositions may be administered via a parenteral route, such as, intraperitoneal, intravenous, subcutaneous, intramuscular, intradermal or transdermal.

In yet a further embodiment, the compositions may be administered via an alimentary route. Exemplary alimentary routes may include, but are not limited to oral, rectal, sublingual or buccal.

Another specific embodiment includes that the compositions may be administered as a dose. It will be understood that a dose can be the amount of the compositions administered to an animal necessary to achieve the desired effect during a given period of time. For example, the dose may be administered as a pill, an oral solution, an injectable solution or an infusable solution, *e.g.*, a patch or a pump. It is contemplated that the dose can be administered at least once a day, but not excluding multiple doses, for example, two or more doses. Also, the dose may be administered pre-prandial. One of skill in the art will realize that the administration of an anti-hyperglycemic agent is governed by the fluctuations of blood glucose in an animal suffering from hyperglycemia. Because the levels of blood glucose can vary based upon a variety of situations, such as exercise, and diet, the administration of the pharmaceutical compositions may be altered to the needs of the animal to maintain glucose homeostasis.

In certain embodiments of the present invention, it is provided herein a method of using the pharmaceutical compositions as an anti-obesity agent. The compositions may be administered to an animal to increase body weight loss. It is contemplated that the increase in body weight loss may be caused by increases in energy expenditure and/or decreases in food intake.

Yet further, it is provided herein a method of using the pharmaceutical compositions as an anti-hyperglycemic agent. The compositions may be administered to an animal suffering from hyperglycemia. Also, the compositions may be administered to an animal to decrease blood glucose levels. It is contemplated that the decrease in blood glucose levels may comprise increases in tissue glucose uptake, which may be mediated by an increase in insulin sensitivity. Also, it is contemplated that the pharmaceutical compositions of the present invention may be administered in combination with a known anti-hyperglycemic agent. Thus, the present invention may be used to augment or